REMARKS

I. STATUS OF THE CLAIMS:

Claims 25, 27 and 29-37 are pending. Claims 25 and 32-37 have been amended. Support for these amendments can be found throughout the specification and claims (See Specification: page 2, line 20 to page 3, line 9). Applicants respectfully submit that no new matter has been added by virtue of these amendments.

II. ELECTION/RESTRICTIONS

In the Office Action the Examiner acknowledges Applicants' election without traverse of Group II drawn to a method of reducing the effect of tranexamic acid, and Applicants' further election of the specie "gastrointestinal side effects". However, the Examiner has indicated that "Applicant did not identify the claims that read on the elected species", therefore, "upon consideration of the elected condition for prosecution on the merits, claims 35 to 37 are identified as reading on the elected species." Accordingly, the Examiner has withdrawn claims 25-36 from consideration and claims 35-37 were examined.

Since the Examiner has identified claims 35-37 as reading on the elected species, it is Applicants' belief that the Examiner intended to withdraw claims 25-34 and not 25-36.

This objection is respectfully traversed. The present invention is directed to oral tranexamic acid formulations that minimize or eliminate the undesirable gastrointestinal side effects in patients receiving oral tranexamic acid therapy (See: page 2, lines 17-18). The entire specification is replete with disclosure about the formulations described therein being suitable for minimizing or eliminating gastrointestinal side effects

associated with prior art formulations of tranexamic acid. Therefore, Applicants believe that it is understood that all of the elected claims read on the elected specie.

In view of the arguments presented above, Applicants respectfully request that claims 25-34 withdrawn by the Examiner be reinstated.

III. REJECTION UNDER 35 U.S.C. § 112

In the Office Action, the Examiner rejected claims 35-37 under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The Examiner stated that in claims 35-37 "there is no indication of what the adverse side effects are or what the adverse side effects are caused by." The Examiner has requested clarification.

Independent claims 25, 32, and 35-37 are directed in part to methods of reducing or decreasing gastrointestinal side effects. It is well known in the art that gastrointestinal side effects include, but are not limited to, nausea, vomiting, diarrhea, bloating and cramping (See: specification at page 2, lines 3-15). It is also clear from the present specification that these side effects can be caused by administration of tranexamic formulations. Therefore, Applicants' have discovered the need for the novel tranexamic acid formulations of the present invention which reduce or eliminate the adverse gastrointestinal side effects that accompany administration of prior art formulations of tranexamic acid.

In view of the arguments presented above, Applicants respectfully submit that the present claims are not indefinite. Therefore, Applicants respectfully request that the Examiner's rejection be removed.

IV. REJECTION UNDER 35 U.S.C. § 102(b)/103(a)

In the Office Action, the Examiner rejected claims 35-37 under 35 U.S.C. § 102(b) on the grounds of being anticipated by or, in the alternative, under 35 U.S.C. § 103(a) as being obvious over U.S. Patent No. 6,197,331 (hereinafter "the Lerner patent"). The Examiner stated:

> "Lerner discloses oral controlled or sustained release formulation that comprises active agent and carrier such as EUDRAGIT polymers…; hydroxypropylmethylcellulose, gelatin, starch and methacrylate… The gelatin, starch, and cellulose are some of the excipients named in applicant's specification as delaying of contributing to the controlled release of the active… Therefore, hydroxypropylmethylcellulose, EUDRAGIT, starch and gelatin meet the requirements for an agent that controls the release. One class of active agent is the hemostatic agents and one of the drugs named in this group of drugs if tranexamic acid which is the same as the recited drug. No specific oral drug form is claimed and the oral delivery dosage form of the prior art meets the drug form that is administered in the instant claims. Vomiting, nausea, gerd, and reflux disease are some of the conditions treated by Lerner… Thus Lerner meets the limitations of the claims."

This rejection is respectfully traversed. Independent claims 25, 32, and 35-37 of the present invention are directed, in part, to methods of treatment with tranexamic acid formulations that: i) "substantially releases (claim 25) or delays release of (claim 37) tranexamic acid in the small intestine; ii) "release… tranexamic acid in both the stomach and intestines" (claims 32, 35); or both i) and ii) (claim 36).

In contrast, the Lerner patent describes controlled release solid compositions or oral patch compositions that adhere to the hard dental surfaces, such as the teeth and dentures, and release the pharmaceutical agent in the oral cavity (See: Lerner: col. 1, lines 9-12; col. 6, lines 38-45; col. 6, line 56 to col. 7, line 19; col. 9, lines 12-58). Nowhere does the Lerner patent teach or suggest that the compositions described therein substantially release or delay release of tranexamic acid in the small intestine, nor does it teach or suggest compositions that release the tranexamic acid in both the stomach and intestines as claimed in the claims of the present invention. Accordingly, independent

claims 25, 32, and 35-37 and the claims that depend there from are not anticipated by nor are they obvious over the Lerner patent.

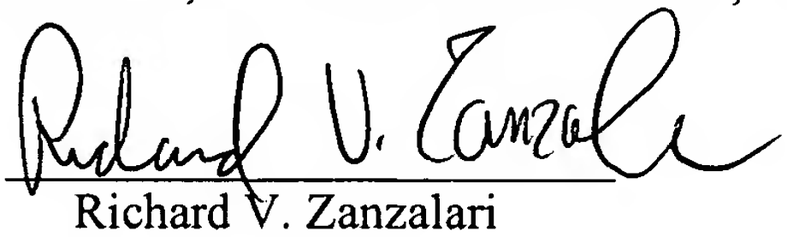
In view of the arguments presented above, Applicants respectfully request that the Examiner's rejections be removed.

V. CONCLUSION

This Amendment is being submitted within 3 (three) months from the mailing date of the Office Action, thus no fees are believed to be due for this Amendment. If it is determined that any fees are due, the Commissioner is specifically authorized to charge said fees to Deposit Account No. 50-0552.

Respectfully submitted,

DAVIDSON, DAVIDSON & KAPPEL, LLC

By: 

Richard V. Zanzalari
Reg. No. 49,032

Davidson, Davidson & Kappel, LLC
485 Seventh Avenue, 14th floor
New York, NY 10018
(212) 736-1940